

REMARKS

Claims

Support for the claim amendment can be found, for example, in the examples of the specification, e.g., page 10, line 6, from the bottom of the page, etc.

The Rejections Under 35 USC § 103

Zettler merely provides general background information for melt extrusion as argued in the last Reply. The Office Action pieces together the claimed invention from the broad disclosure of Zettler and alleges that the claimed invention is obvious because Zettler discloses that for the purposes of their invention the particular species are equivalent. In this regard, applicants request that the Office Action point out where such equivalency of species is disclosed in Zettler.

Additionally, even if such equivalency were taught, which it is not, Zettler does not teach a species of the claimed invention. Zettler describes various large lists of, e.g., active ingredients, plasticizers, binders, various additives, etc., which were pointed out in the last Reply. These lists are quite broad and do not describe or even suggest a species of the claimed invention.

The test of obviousness is not whether one can piece together an invention from the broad disclosure of prior art, but whether there is adequate motivation for the combination. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). As the Examiner well knows, the law requires that there be some suggestion or teaching in the prior art that provides the motivation for one of ordinary skill in the art to arrive at the claimed invention. Such teaching or suggestion is completely absent here. Moreover, the Office Action fails to allege any motivation for the asserted modification of the prior art.

Zettler also explicitly points away from using plasticizers as a whole, one of the choices for plasticizer being polyvinylpyrrolidone in Zettler. The Office Action responds to arguments made on this issue by stating that Zettler's disclosure cites the absence of plasticizers as a preference, not a prohibition. However, a prohibition is not required for it to be a teaching away. A teaching away from a combination is a relevant fact when determining whether motivation is

provided for the claimed combination. See *Alza Corp. v. Mylan Laboratories Inc.*, 73 USPQ2d 1161 (CA FC 2004). In deciding whether this reference provides motivation to one of ordinary skill in the art to select a plasticizer as an ingredient of a composition, one must consider the fact that the reference teaches a preference for the absence of a plasticizer. In the present case the obviousness rejection cannot stand due to the lack of motivation, and, additionally, the teaching away as discussed above.

Budavari teaches additional active ingredients, but does not overcome the deficiencies of the primary reference.

Reconsideration is respectfully requested.

The Rejections Under 35 USC § 102

Meignant is alleged to anticipate. The Office Action points to the formulation disclosed on column 6, lines 15-20.

Meignant does not teach an extrudate and also does not teach that the estradiol is micronized. As such, the claims are not anticipated. Moreover, Meignant also does not suggest the claimed invention.

The Commissioner is hereby authorized to charge any fees, including extra claim fees, extension fees and RCE fees, associated with this response or credit any overpayment to Deposit Account No.

13-3402.

Respectfully submitted,

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